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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/089,611	06/27/2002	Pavuluri Venkateswara Rao	13102.6USWO	3079

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MERCHANT & GOULD PC  
P.O. BOX 2903  
MINNEAPOLIS, MN 55402-0903

EXAMINER
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TRAN, SUSAN T

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 12/15/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/089,611

Applicant(s)

RAO ET AL.

Examiner

Susan T. Tran

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 9. 6) ☐ Other: .

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### **DETAILED ACTION**

Receipt is acknowledged of applicant's Declaration filed 06/21/02, Amendment A filed 06/27/02, Corrected Filing Receipt and Information Disclosure Statement filed 09/02/03.

#### ***Specification***

This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

#### ***Claim Objections***

Claim 9 is objected to for missing a period at the end of the claim. Appropriate correction is required.

Claims 1 and 5 are objected to in the use of the word "solublising". What is "solublising"?

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 9 are rejected in the use of the phrase "and related ailments" in line

3. What are the related ailments?

Regarding claims 2-7, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Regarding claims 2, 4, 7 and 8, the phrase "and the like" renders the claim indefinite because it includes elements not actually disclosed (those encompassed by "and the like"), thereby rendering the scope of the claim unascertainable. See MPEP § 2173.05(d).

Claims 3, 5 and 6 are rejected in the use of the phrase "preferably", which is considered a range within a range. It is unclear whether the limitations following the phrase are part of the claimed invention or just exemplary.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee et al. Korea Patent No. 0131375, and Thacharodi et al. EP 0 960 620.

Lee teaches a storage stable omeprazole composition comprising omeprazole, triethanolamine, corn oil, and glycerylmonostearate (pages 3, second paragraph). The

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composition can be formulated into soft gelatin capsule, and the capsule is coated with mixture of plasticizer and film-coating polymer, including, hydroxypropylmethyl cellulose phthalate or cellulose acetate phthalate. Lee does not teach the surfactant and the dispersing agent.

Thacharodi teaches a stable oral pharmaceutical composition containing mixture of substituted benzimidazole, polyvinylpyrrolidone (pvp), and other excipients, including talc and vegetable oils (pages 4-5). The composition can be formulated in an enteric capsule (ID). Thus, it would have been obvious for one of ordinary skill in the art to, by routine experimentation modify the stable omeprazole composition of Lee in view of the teaching of Thacharodi to obtain the claimed invention, because the references teach a stable formulation to deliver omeprazole to small intestine without degradation in the stomach.

Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chen et al. US 2003/0129235 A1, in view of Lindberg et al. US 5,714,504.

Chen teaches a pharmaceutical composition comprising proton pump inhibitor with or without NSAID (see abstract, and paragraph 0050). The proton pump inhibitor includes, omeprazole, lansoprazole, pantoprazole, and other benzimidazole compounds (paragraph 0042). The proton pump inhibitor is employed in admixtures with conventional excipients, including vegetable oil, magnesium stearate, talc, pvp, lubricant and stabilizer (paragraphs 0047 and 0052). Chen also teach that proton pump inhibitor can be mixed with alkaline compounds (paragraph 0053). The formulation is then

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coated with an enteric coating layer to protect contact with gastric juice until the dosage form reaches the gastrointestinal tract, where pH is near neutral (paragraph 0045). The coated formulation can be incorporated into soft gelatin capsule (paragraph 0062).

Chen does not teach the capsule can be enterically coated.

Lindberg teaches an omeprazole composition that can be formulated in soft gelatin capsule, and the capsule can be enteric-coated to prevent degradation in the stomach (column 5, lines 25-50). Thus, it would have been obvious for one of ordinary skill in the art to optimize the omeprazole composition of Chen using the soft gelatin capsule in view of the teaching of Lindberg, because the references teach the use of enteric coating to prevent degradation of active ingredient in gastric juice.

Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chen et al. US 2003/0129235 A1, in view of Thacharodi et al.

Chen teaches a pharmaceutical composition comprising proton pump inhibitor with or without NSAID (see abstract, and paragraph 0050). The proton pump inhibitor includes, omeprazole, lansoprazole, pantoprazole, and other benzimidazole compounds (paragraph 0042). The proton pump inhibitor is employed in admixtures with conventional excipients, including vegetable oil, magnesium stearate, talc, pvp, lubricant and stabilizer (paragraphs 0047 and 0052). Chen also teaches that, alternatively, proton pump inhibitor can be mixed with alkaline compounds (paragraph 0053). The formulation is then coated with an enteric coating layer to protect contact with gastric juice until the dosage form reaches the gastrointestinal tract, where pH is near neutral

(paragraph 0045). The coated formulation can be incorporated into soft gelatin capsule (paragraph 0062).

Chen does not teach the capsule can be enterically coated.

Thacharodi teaches a stable oral pharmaceutical composition containing mixture of substituted benzimidazole, polyvinylpyrrolidone (pvp), and other excipients, including talc and vegetable oils (pages 4-5). The composition can be formulated in a soft gelatin enteric capsule (ID). Thus, it would have been obvious for one of ordinary skill in the art to, by routine experimentation modify the omeprazole composition of Chen using the gelatin capsule in view of the teaching of Thacharodi to obtain the claimed invention, because the references teach a stable formulation to deliver omeprazole to small intestine without degradation in the stomach.

### ***Pertinent Arts***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Fujishima et al. is cited as being of interest for the teaching of formulation containing benzimidazole compound.

### ***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan T. Tran whose telephone number is (703) 306-5816. The examiner can normally be reached on Monday through Thursday from 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page, can be reached at (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

  
THURMAN K. PAGE  
SUPERVISORY PATENT EXAMINER  
TECHNICAL CENTER 1600